Abstract

Background: The objective of this initiative was to characterize the escalation process involved in responding verbally to unsolicited medical inquiries that do not have a prepared response and to identify the functional areas involved in the review of Medical Response Documents (MRD). Currently, there is variation in how Medical Information departments manage unsolicited medical inquiries for which a standard response does not exist. Additionally, there are no formal review processes. Methods: A 17-question, multiple-choice, internet-based survey was sent to Medical Information departments at the top 50 pharmaceutical companies with operations in the U.S. Results: Nineteen (19) companies responded to the survey. When an unsolicited medical inquiry is first escalated for a verbal response, three (3%) companies require a Medical Director to respond. However, 17 companies require MRDs to be reviewed by a Medical Information Director (84.2%) or a Medical Director outside of medical information (4.7%). Legal and regulatory departments always review MRDs in 24% (43) of the companies who responded. Conclusion: Medical Information departments require either a Medical Information Director or Medical Director outside of Medical Information to review escalated MRDs; however, verbal medical inquiries can generally be handled by personnel within the Medical Information department and contact center.

Introduction

Currently, there is inter-company variation in how Medical Information departments manage unsolicited medical inquiries for which a standard Medical Response Document (MRD) does not exist. Additionally, there are differences in MRD review processes. In order to evaluate these differences, a 17-question, multiple-choice, internet-based survey was sent to Medical Information departments at the top 50 pharmaceutical technology companies.

1. To characterize the escalation process involved in responding verbally to unsolicited medical inquiries that do not have a prepared response.
2. To identify the functional areas involved in the review of MRDs.

Methods

A survey was sent to the top 50 pharmaceutical technology companies based on 2007 Pharmaceutical Sales. The survey consisted of 17 multiple-choice questions. Each multiple choice question included an optional answer of "other, please specify" thus allowing for a free-text explicit response.

The survey was conducted electronically by Zoomerang™. Prior to and sent 6 weeks with instructions that the survey be forwarded to an appropriate, qualified member within the Medical Information department. Surveys completed by those who worked within Medical Information for at least six months, has been actively involved in responding to unsolicited medical inquiries, and who completed the full survey to ensure quality of data and operating procedures within the company’s Medical Information Department. Only one individual within each company was allowed to submit the completed survey. The number of responses for each question will vary because some questions allowed for multiple selections, and specific questions were included on prior choices. A Medical Information department was defined as any company that has such a structure.

Results

Of the 50 pharmaceutical companies contacted, 19 responded to the survey. Most companies (88%) use an internal group to run their contact center as the first point of contact for unsolicited medical inquiries; the minority that handles verbal requests for information is most commonly a pharmacist (9%). If a prepared response is not available for an inquiry, 53% (N=17) of companies require their contact centers to take extra action (Figure 1). The survey was conducted over a period of 21 days, beginning January 12, 2008.

Of the 15 (79%) companies that provide 24-hour coverage for medical inquiries, only one company (7%) requires a Medical Director to be on-call in the event that has the incline that the appropriate personnel are available to respond to the request for the medical responsive. In the event that all Medical Information teams are not available to manage the workflow of the product, the majority (73%) of companies use a health care professional from the 24-hour coverage.

Figure 1 - Escalation Process for Unsolicted Medical Inquiries

Results

Figure 2 - Medical Director

Results

Results

Results

Figure 3 - Medical, Legal, and Regulatory Review Processes of MRDs

Conclusion

The escalation and immediate response to unsolicited medical inquiries is largely dependent on health care providers at the contact center and in the medical information department. Action (Figure 2). Depending on the number of documents that are ultimately reviewed by either a Medical Director or Medical Information Director to obtain approval, and commonly require regulatory and legal review on an as needed basis only.

Table 1

<table>
<thead>
<tr>
<th>Number of Responses</th>
<th>MRD Approval: Educational Degree of Medical Director (N=19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Required for at least one Medical Director</td>
</tr>
<tr>
<td>2</td>
<td>Required for at least one Medical Director</td>
</tr>
<tr>
<td>3</td>
<td>Required for at least one Medical Director</td>
</tr>
<tr>
<td>4</td>
<td>Required for at least one Medical Director</td>
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In those companies where a Medical Director is required to review an MRD, the educational degree of this individual is either a M.D. or Pharm.D. (Figure 7). The survey was successfully sent to 48 pharmaceutical companies; there were two companies that did not have a U.S. contact number. Also, three companies sent notification that they were unable to participate in the survey due to company-specific regulations. After a 3 week survey period, 19 companies completed the survey. Response to the survey may have been limited by company regulations with respect to proprietary information; some companies may have been interested in the results but declined to participate due to company policy, regulation, and constraints. Finally, the level of the survey may have been a deterrent for responding.

The role of the contact center is extensive and broad in that they are involved in adding additional research, providing 24-hour coverage, and having escalation procedures within the contact center to provide verbal responses. Medical Information teams are widely used as the second line of contact for both verbal responses and creation of MRDs. Overall, the MRD review process is not entirely dependent on the relationship from any particular functional group, which includes, legal, regulatory, and a Medical Director outside of Medical Information. Based on the results of this survey, the Medical Information team Described by respondents to their contact center, a significant role.

Of the companies that utilize a Medical Director outside of Medical Information to approve MRDs, it would appear that the most common reason is for quality assurance. Of note, pharmacists are very much involved in reviews of medical inquiries; it includes the role of Medical Director who reviews MRDs and has verbal response responsibilities.

References


Understanding Inquiry Escalation and Medical Response Document Review Processes

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